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510(k) SUMMARY

a) Applicant Information:

Date Summary Prepared	09 February 2009
Sponsor/Submitter	Avantis Medical Systems, Inc. 263 Santa Ana Court Sunnyvale, CA 94085-4511
Correspondent Contact Information	Amrita Sethi Director of Regulatory and Quality Affairs Phone: 408-733-1901 x227 Fax: 408-733-1847 E-mail: asethi@avantismedical.com

b) Device Information:

Device Common Name	Endoscope
Device Trade & Proprietary Name	Third Eye® Retroscope® Auxiliary Endoscopy System (Third Eye)
Device Classification Name	Colonoscope (per 21CFR 876.1500)
Device Classification Regulation	21CFR 876.1500
Device Classification	Class II (special controls)
Device Classification & Product Code	FDF, FDS, KNW, KOG

c) Identification of Predicate Device:

The Avantis Third Eye is substantially equivalent in operation and fundamental scientific technology to its previous version, cleared under K070330.

d) Device Description Summary:

The Third Eye System consists of both disposable portions and facility equipment. The disposable portions include the Third Eye Retroscope and Caps. The facility equipment portions of the device include the Third Eye Video Processor and accessories.

The Third Eye is designed as an auxiliary device for use during a colonoscopy

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procedure. After a colonoscope has been advanced to the cecum, the Third Eye Retroscope is inserted through the instrument channel of the colonoscope. As the Third Eye Retroscope emerges from the distal tip of the instrument channel of the colonoscope, it automatically bends 180 degrees to form a "J" shape. The Third Eye then provides a continuous retrograde image of the colon throughout the process of withdrawal of the colonoscope.

The Third Eye Video Processor is a piece of electrical equipment that acts as an interface for the Third Eye Retroscope, the video output signals, and user input controls. The output video signals from the Video Processor are displayed on a monitor for viewing by the physician. Application software that runs on the Video Processor allows the user to adjust the light intensity and various picture settings of the Third Eye Retroscope image.

e) **Intended Use:**
The Third Eye Retroscope is intended for use in the instrument channel of a conventional colonoscope to provide retrograde illumination and visualization of the colon for diagnostic purposes.

f) **Discussion of Substantial Equivalence to Predicate Device:**
The Third Eye has been modified to a) accommodate additional conventional colonoscope models and brands, b) provide product enhancements, c) improve manufacturability, and d) update software. The modified device is substantially equivalent to the cleared predicate device in fundamental design materials, processes, sterile barrier packaging, and sterilization. All changes have been subjected to risk analysis and have been verified to meet current design specifications.

The IFU has been updated to a) add clinical data, b) clarify procedural directions based on the clinical experiences and c) expand the indications for use based on clinical data demonstrating that the Third Eye used with a traditional colonoscope improves detection of polyps and adenomas during colonoscopy as compared to the use of a colonoscope alone.

Differences between the modified Third Eye System and the predicate device have no impact on safety and effectiveness.

g) **Scientific Technology**
The Third Eye® Retroscope® Auxiliary Endoscopy System includes the Retroscope, a Video Processor, Cap and accessories. Modifications made to the device and accessories did not change the fundamental scientific technology of the device. The testing described demonstrates that the differences in the device components and

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accessories do not raise any new or unresolved issues for safety and efficacy.

h) **Summary of Supporting Non-Clinical Performance Data**
Bench verification testing was conducted to verify that the modified device meets the design inputs and intended performance characteristics. Results demonstrate that modifications made to the Third Eye design performs as intended.

i) **Summary of Supporting Clinical Data**
Results from a prospective, multi-center post-market study demonstrate that retrograde viewing of the colon with the Third Eye improves the detection of polyps and adenomas compared to traditional colonoscopy alone. Results were statistically significant.

j) **Conclusions**
Avantis Medical Systems, Inc. has determined, based on clinical data, that the Third Eye improves the detection of polyps and adenomas in patients for whom colonoscopies are indicated. Risks to patients in terms of adverse events are comparable to those reported in the literature for traditional screening colonoscopies. Use of the Third Eye did not increase the risks to the patients but offered a statistically significant benefit of improved detection. Results of the clinical study are included in the Instructions for Use.

Any statement regarding "substantial equivalence" made in this 510(k) submission and summary only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any *patent proceeding, including patent infringement, litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.*

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2009

Ms. Amrita Sethi
Director of Regulatory and Quality Affairs
Avantis Medical Systems, Inc.
263 Santa Ana Court
SUNNYVALE CA 94085-4511

Re: K083180
Trade/Device Name: Third Eye® Retroscope® Auxiliary Endoscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF and ODA
Dated: February 4, 2009
Received: February 5, 2009

Dear Ms. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083180

Device Name: Third Eye® Retroscope® Auxiliary Endoscopy System (Third Eye)

Indications for Use: The Avantis Medical Systems, Inc. Third Eye is indicated for use in the instrument channel of a conventional colonoscope to provide retrograde illumination and visualization of the colon for diagnostic purposes.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083180